JUL 12 2011 K110670 1/2

510(k) Summary of Safety and Effectiveness

VLP FOOT Talus Bone Plates, VLP FOOT Percutaneous Calcaneus Bone Plates, VLP Bone Screws, PERI-LOC Ankle Fusion Bone Plates and Device Specific Instruments

Submitted By:

Smith & Nephew, Inc.
Orthopaedics
1450 Brooks Road
Memphis, TN 38116

Date: July 07, 2011

Contact Person:

David Henley, Regulatory Affairs Project Manager
Tel: (901) 399-6487 Fax: (901) 566-7079

Proprietary Name: **VLP FOOT Talus and Percutaneous Calcaneus Bone Plates, VLP Bone Screws; PERI-LOC Ankle Fusion Bone Plates and Instruments**

Common Name: Bone Plates and Bone Screws

Classification Name and Reference: 21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories - Class II

21 CFR 888.3040, Smooth or threaded, metallic bone fixation fastener - Class II

Device Product Code and Panel Code: HRS / HWC / Orthopedics / 87

Device Description:

The subject devices are comprised of locking bone plates and locking and non-locking bone screws. All described implant components are manufactured from stainless steel material. The subject implant devices are available in the following size ranges:

Device Type	Available Length Range
VLP 2.5mm Talus Plates	20 – 25mm
PERI-LOC 3.5mm Anterior Primary Ankle Fusion Plates	66 – 92mm
PERI-LOC 3.5mm Hindfoot Ankle Fusion Utility Plates	79 – 104mm
PERI-LOC 3.5 and 4.5mm Posterior Ankle Fusion Plates	80mm
PERI-LOC 4.5mm Lateral Tibiotalocalcaneal Ankle Fusion plates	120mm
VLP 2.7mm Percutaneous Calcaneus Plates	55 – 62mm
VLP 2.5mm T7 Locking Cortex Screws	6 – 50mm
VLP 2.7mm Locking Cortex Screws	42 – 50mm
VLP 4.0mm Fully Threaded Osteopenia Screws	42 – 50mm
VLP 4.0mm Locking Osteopenia Screws	42 – 50mm
VLP 4.0mm Partially Threaded Osteopenia Screws	42 – 50mm

Device specific instruments are also described in this premarket notification in select sections and exhibits.

Intended Use:

The Smith & Nephew VLP FOOT Plating System can be used in adolescent (12-18 years) and transitional adolescent (18-21 years) subpopulations and adults, as well as patients with osteopenic bone. The VLP FOOT Plating System is indicated for fracture fixation, reconstruction or arthrodesis of small bones, including those in the forefoot, midfoot and hindfoot.

The Smith & Nephew PERI-LOC Ankle Fusion Plating System can be used in adolescent (12-18 years) and transitional adolescent (18-21 years) subpopulations and adults, as well as patients with osteopenic bone. The PERI-LOC Ankle Fusion Plating System is indicated for ankle arthrodesis and fractures, including the distal tibia, fibula and calcaneus.

Technological Characteristics:

Components comprising **VLP FOOT Talus plates, VLP FOOT Percutaneous Calcaneus plates, VLP Bone Screws** and **PERI-LOC Ankle Fusion plates** are very similar to legally marketed devices listed below cleared under K090675, K033669, K993106, K071264, K060473, K073375 and K022255. When compared to the predicates, the proposed devices share very similar indications for use and intended use, are manufactured from similar materials, and incorporate very similar technological design characteristics. The **device specific instruments** described in this premarket notification are also similar to the identified predicate devices cleared under K092497 and K100107.

Substantial Equivalence Information:

When compared to the implant and device specific instrument predicate devices listed below, substantial equivalence is based on similarities with regard to overall indications for use, material composition, and technological design characteristics.

- VLP FOOT Plating and Screw System – K090675
- PERI-LOC Periarticular Locked Plating System – K033669
- TC-100 Plating and Screw System – K993106
- Synthes 2.4mm/2.7mm Locking Foot Module – K071264
- Synthes Ankle Arthrodesis Plates – K022255
- TTC Plate (Newdeal SAS/Integra Life Sciences, Corp.) – K060473
- Newdeal TIBIAXYS System – K073375
- Smith & Nephew Pigalileo Screw Targeting System, Ver. 1.1 – K092497
- Smith & Nephew Sureshot Distal Targeting System, Ver. 2.0 – K100107

To further support a determination of substantial equivalence, various types of pre-clinical testing were conducted on the subject, implantable devices in comparison against one or more of the previously cleared predicate devices described above. The specific types of pre-clinical testing included:

- *Engineering analysis*
- *Four-point bend fatigue* testing of plates
- *Construct fatigue testing* of plate/screw constructs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

JUL 12 2011

Smith & Nephew, Inc.
% Mr. David Henley
1450 Brooks Road
Memphis, TN 38116

Re: K110670
Trade/Device Name: VLP FOOT Plating System and PERI-LOC Ankle Fusion Plating System – Locking Bone Plates and Screws
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: June 30, 2011
Received: July 1, 2011

Dear Mr. Henley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number (if known): K110670

Device Name: VLP FOOT Plating System and PERI-LOC Ankle Fusion Plating System - Locking Bone Plates and Screws

Indications for Use:

The Smith & Nephew VLP FOOT Plating System can be used in adolescent (12-18 years) and transitional adolescent (18-21 years) subpopulations and adults, as well as patients with osteopenic bone. The VLP FOOT Plating System is indicated for fracture fixation, reconstruction or arthrodesis of small bones, including those in the forefoot, midfoot and hindfoot.

The Smith & Nephew PERI-LOC Ankle Fusion Plating System can be used in adolescent (12-18 years) and transitional adolescent (18-21 years) subpopulations and adults, as well as patients with osteopenic bone. The PERI-LOC Ankle Fusion Plating System is indicated for ankle arthrodesis and fractures, including the distal tibia, fibula and calcaneus.

VLP FOOT Plating System and PERI-LOC Ankle Fusion Plating System bone plates and bone screws are for single use only.

Prescription Use X AND/OR Over-the-Counter Use
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110670